



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/973,609	10/09/2001	Shlomo Gabbay	SHEP5010US	8158

26294 7590 01/29/2007
TAROLLI, SUNDHEIM, COVELL & TUMMINO L.L.P.
1300 EAST NINTH STREET, SUITE 1700
CLEVEVLAND, OH 44114

EXAMINER

PELLEGRINO, BRIAN E

ART UNIT	PAPER NUMBER
----------	--------------

3738

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/973,609	GABBAY, SHLOMO	
	Examiner	Art Unit	
	Brian E Pellegrino	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-28, 51, 52 and 61-70 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-28, 51, 52 and 61-70 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

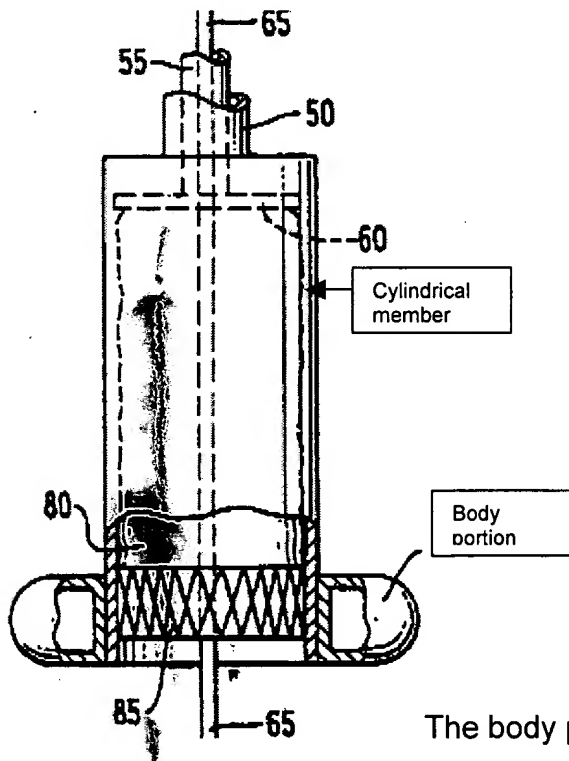
- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 21,28,51,61-63,67,70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stevens (5370685). Fig. 9 shows an implantation system with an elongate cylindrical member with an inner diameter that falls within the claimed range of 5-15mm since the inner channel 50 has dimensions as minimal as 0.5mm, the outer channel or cylindrical member would have dimensions clearly falling within the claimed range, col. 7, lines 65,66. It can also be seen there is a body portion as seen below.



The body portion and cylindrical member being coaxial and the body portion having a greater diameter than the cylindrical member. It can also be seen mounted within the system is a heart valve prosthesis with a generally

cylindrical support **85** having a valve fixed between the ends of the support. Fig. 10 illustrates the system includes a plunger **60** to urge the prosthesis from the cylindrical member. Stevens discloses the valve can be natural tissue heart valve, col. 9, lines 7-13. Stevens also discloses the support structure can be made of shape memory like material, col. 9, lines 23-29. Figs. 11 & 12 show projections **90** biased to extend radially from the support. However, Stevens fails to disclose the cylindrical member extends to terminate in an opening spaced longitudinally apart from the body member. It would have been an obvious expedient to have the cylindrical member terminate apart from the body member such that it enables the surgeon to deliver the prosthesis to an area that is at a distance from the area where the delivery device can be stabilized for the surgeon to precisely place the implant. Since applicant has not disclosed that using a spaced body member from the terminating end of the cylindrical member provides any advantage, or solves a stated problem, or is used for any particular purpose a modification of the implantation system is within the level of ordinary skill in the art.

Regarding claim 28, Stevens fails to disclose the use of a pulmonic valve. It would have been an obvious matter of design choice to modify the type of valve used, since applicant has not disclosed that using a pulmonic valve provides any advantage, or solves a stated problem, or is used for any particular purpose. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the type of valve chosen as taught by Stevens such that it corresponds to the one being replaced or the claimed pulmonic valve in claim(s) 28 because both heart valve prostheses perform the same function of being restrained in a first condition in a

delivery device and then expanded into a second condition when implanted and provides a functioning valve replacement.

Claim 52 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stevens '685 in view of Torossian (5851210). Stevens is explained supra. However, Stevens fails to disclose indicia on the cylindrical member. Torossian teaches (Fig. 2) indicia 54 are placed on the cylindrical member or catheter. Torossian additionally teaches the indicia are used to facilitate implantation of the device, col. 6, lines 26-28. It would have been obvious to one of ordinary skill in the art to incorporate indicia on the cylindrical member as taught by Torossian with the implantation system of Stevens such that it enables the surgeon to accurately place the valve in the location desired and know when it is at the implantation site by the use of the indicia.

Claims 22-26, 65, 66, 68, 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stevens '685 in view of Shokoohi et al. (6077296). Stevens is explained above. However, Stevens fails to disclose the support structure including biasing elements. Shokoohi et al. teaches (Fig. 2) an expandable prosthesis with a plurality of support features 54 joined by connecting element 56. It can also be seen at the proximal and distal ends 55, 59 that the projections extend radially outward and are triangular. Shokoohi also teaches that suture can be used to limit the outward expansion, col. 7, lines 32-39. Shokoohi also shows (Fig. 11) that the support features can have springs 60 at the ends for receiving the suture so sections attached will not separate. It would have been obvious to one of ordinary skill in the art to incorporate

Art Unit: 3738

biasing elements as taught by Shokoohi with the prosthesis of Stevens such that it has enhanced securing means to hold a longer prosthesis together.

Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stevens '685 in view of Vesely et al. (5549665). Stevens is explained supra. However, Stevens fails to disclose the use of a sheath to cover the exposed parts of the support. Vesely et al. teach to cover the exposed parts of the stent support (Figs. 2,4) using a sheath or covering **35**. It would have been obvious to one of ordinary skill in the art to use a sheath as taught by Vesely with the prosthesis of Stevens such that the stent support is covered to provide a smooth surface so no rigid structure can cause trauma to the surrounding tissue. Additionally, the sheath would prevent contact of the metal support with surrounding tissue and eliminate any possibility of irritation or allergic reaction to metal.

Claim 64 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stevens '685 in view of Del Toro (5733267). Stevens is explained above. However, Stevens does not disclose a handle portion attached to the body of a cylindrical member for delivering the prosthesis. Del Toro teaches (Fig. 4) a handle **40** attached to the body of a cylindrical delivery device **32**. It would have been obvious to one of ordinary skill in the art to use a handle as taught by Del Toro with the delivery device of Stevens such that the surgeon can accomplish accurate control of the delivery device.

Response to Arguments

Applicant's arguments filed 11/1/06 have been fully considered but they are not persuasive. The Applicant argues that the prosthesis is not mounted within a channel with the dimensions as claimed or having the body member spaced from the opening of the cylindrical member. The longitudinal spacing of the body member from the cylindrical member is addressed above and since the Applicant presented no reasoning or where support in the written disclosure for this new limitation as to why this is critical, it clearly is an obvious matter of design choice. Regarding the prosthesis within the cylindrical member, it clearly can be seen that Fig. 9 in the Stevens patent '685 shows the valve prosthesis in the cylindrical member and the dimensions would fall within the claimed range if considering the dimensions of the inner channel and the relative dimensions of other members of the system with respect to one another, it would have a dimension within "about" 5-15mm. The other combination of rejections are within the level of ordinary skill in the art to modify the implantation system and prosthesis for obvious improvements.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E Pellegrino whose telephone number is 571-272-4756. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached at 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TC 3700, AU 3738

BRIAN E. PELLEGRINO
PRIMARY EXAMINER

Brian E Pellegrino